#### REMARKS

The Office Action dated June 17, 2003 has been carefully reviewed and the foregoing remarks are made in response thereto. In view of the above claim amendments and following remarks, Applicant respectfully requests reconsideration and reexamination of this application and timely allowance of the pending claims.

By this Amendment, claims 18, 20-23, 26, 29, 34, 37-39 and 44 have been canceled and new claims 97-124 have been substituted therefor. Applicant respectfully submits that substitute claims fall within the subject matter of the elected invention and that no new prohibited matter has been introduced by the amendments. While written description support for the claims can be found throughout the specification, examples of specific support for the additional claims can be found in the original claims and specification as set forth in the table below.

Claim	Support in Specification
97-100, 105-110, 122-124	original claim 18, page 29 (example 3)
101	original claim 11, page 22, lines 22-25
102, 104	page 39 (table 9)
103	page 13, lines 25-27
111-114, 118-121	page 22, lines 28-29
115-117	original claim 18, page 29 (example 3)

# **Summary of the Office Action**

- 1. The disclosure was objected to as not being in compliance with the 37 C.F.R. 1.821 requirement that all nucleotide sequences presented in an application have sequence identifiers.
- 2. Claims 22, 23, 29, 38, 39 and 44 were rejected under 35 U.S.C. 112 (first paragraph) as failing to comply with the written description requirement.
- 3. Claims 18, 20-23, 26, 29, 34, 37-39 and 44 were rejected under 35 U.S.C. 112 (second paragraph) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.
- 4. Claims 18, 20-23, 26, 29 and 44 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,763,183.
- 5. Claims 34 and 39 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,578,443

6. Claims 37 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,578,443.

### Objection based on 37 C.F.R. 1.821

The as-filed specification was objected to for not containing sequence identifiers when referring to a specific amino acid or nucleotide sequence. Applicant has amended the specification to comply with the sequence rules by inserting sequences and sequence identifiers where necessary. Applicant submits that no new matter has been added by this amendment.

# Rejection based on 35 U.S.C. 112 (first paragraph)

Claims 22, 23, 29, 38, 39 and 44 were rejected under 35 U.S.C. 112 (first paragraph) for purportedly failing to comply with the written description requirement. Applicant has cancelled these claims, therefore the rejection is moot. In light of the substitute claims, however, Applicant submits that the claims are drawn to a method of determining the haplotype of a single gene (BRCA1) which is adequately supported by the specification. Applicant brings to the Examiner's attention the experimental data disclosed in the specification in Example 3 (page 29), where methods are disclosed for determining different haplotypes for the BRCA1 gene along with multiple examples of such haplotypes identified by these methods.

### Rejection based on 35 U.S.C. 112 (second paragraph)

Claims 18, 20-23, 26, 29, 34, 37-39 and 44 were rejected under 35 U.S.C. 112 (second paragraph) for purportedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant has cancelled these claims, therefore the rejection is moot. Applicant submits that the substitute claims do not contain any of the rejected terms (*i.e.*, "wild-type") from the cancelled claims.

### Rejections based on 35 U.S.C. 102(e)

Claims 18, 20-23, 26, 29 and 44 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,763,183. Applicant has cancelled these claims, therefore the rejection is moot. In light of the substitute claims, however, Applicant submits that the substitute claims are not anticipated by the cited reference. The substitute claims recite the feature that the BRCA1 haplotype be determined in the claimed

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method by comparison to SEQ ID NO: 263 (BRCA1-omi1). Applicants bring to the Examiner's attention that there is no mention of the BRCA1 gene or even BRCA1-omi1 in the cited reference.

Rejection based on 35 U.S.C. 103(a)

Claims 37 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

5,578,443. These claims were cancelled, therefore the rejection is moot. With regard to the substitute

claims, Applicant submits that the cited reference does not disclose, nor suggest the feature of determining

the BRCA1 gene haplotype of the claimed method.

Conclusion

The foregoing remarks are being made to place the application in condition for allowance.

Applicant respectfully requests reconsideration and timely allowance of the pending claims. A favorable

action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of

this application, she is invited to telephone the undersigned at her convenience.

If there are any fees due in connection with the filing of this amendment, please charge the fees to

our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not

accounted for above, such an extension is requested and the fee should also be charged to our Deposit

Account.

**Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this

paper to charge any additional fees during the entire pendency of this application including fees due under

37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit

any overpayment to Deposit Account 50-0310. This paragraph is intended to be a constructive petition

for extension of time in accordance with 37 C.F.R. 1.136(a)(3).

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Respectfully submitted

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